U.S. Department of Agriculture's Bovine Spongiform Encephalopathy Surveillance Plan
Questions and Answers
March 18, 2004

For more than a decade, the U.S. Department of Agriculture (USDA) has taken aggressive measures to prevent the introduction and potential spread of bovine spongiform encephalopathy (BSE). The most recent measures were announced on March 15, and involve a 12-18 month program to enhance surveillance of the cattle population for disease detection and eradication purposes.

Q. Why is USDA taking these additional measures?

A. USDA is committed to ensuring that a robust surveillance program for BSE continues in this country. Following the finding of the single BSE-positive cow in the United States, the Secretary requested an international expert BSE panel review USDA's efforts to ensure the safety of the U.S. food supply. This surveillance plan is based on the panel's recommendations.

Q. How has USDA conducted BSE surveillance until this point?

A. USDA's BSE surveillance program has historically focused on the cattle populations considered to be at highest risk for the disease, specifically, nonambulatory cattle, cattle condemned at slaughter for signs consistent with disorders of the central nervous system, and cattle that die on farms. It is in these populations that we would be most likely to find the diseaseand by focusing our surveillance efforts on these higher risk animals, we have increased the likelihood of finding the disease. In FY 2004, USDA

sampled 20,543 animals—a sample size designed to detect the disease if it occurred in 1 animal per million adult cattle with a 95 percent confidence level. This sample size is more than 47 times the international standard for countries with a low BSE risk.

Under the enhanced program, using statistically geographic modeling, sampling some 268,000 animals would allow for the detection of BSE at a rate of 1 positive in 10 million adult cattle with a 99 percent confidence level. In other words, the enhanced program could detect BSE even if there were only five positive animals in the entire country. Sampling some 201,000 animals would allow for the detection of BSE at the same rate at a 95 percent confidence level.

Q. How is the new surveillance plan different?

A. Historically, over the past 14 years or so, USDA's BSE surveillance program has focused on cattle populations considered to be the highest risk of having the disease--animals that are exhibiting central nervous system disorders, nonambulatory cattle, and those that die on the farm of unknown causes.

The objective for USDA's new surveillance program is to obtain samples from as many of this targeted high-risk population as is possible as well as to obtain a random sample of the normal, but older animals at slaughter. This intensive effort will allow the Department to more definitively determine if BSE exists in our national herd and, if so, accurately estimate the prevalence of the disease in the U.S. cattle population.

Under this surveillance plan, USDA will test as many of these cattle as possible for a 1 to 1 _ year period. For example, based on a statistically geographical modeling, under the enhanced plan, if a total of 201,000 samples is collected, this level of sampling

would allow for the detection of BSE at a rate of 1 positive in 10 million adult cattle with a 95 percent confidence level. And, if a total of at least 268,500 samples is collected, this level of sampling would allow for the detection of BSE at the same rate at a 99 percent confidence level. Such a system will allow USDA to more accurately estimate the possible prevalence of BSE in the U.S. cattle population.

In addition to sampling the high-risk population, USDA will also conduct some random sampling of apparently normal, aged slaughter cattle. This is consistent with the recommendations of the international panel that reviewed the U.S. system for preventing and detecting BSE in the United States. The objective is to include in the testing some subset of animals that would have been born before North American bans on feeding ruminant protein to other ruminants. We believe this is a prudent measure to take in our effort to better define the prevalence at which BSE is present in the United States.

In addition, whereas all BSE testing in the United States has historically been performed at USDA' National Veterinary Services Laboratories (NVSL), the new program incorporates a network of State and university laboratories into the testing program.

Q. How long will this amplified surveillance last?

A. USDA will begin immediately to prepare for the increased testing, with the anticipation that the program will be ready to be fully implemented June 1, 2004. Testing will be conducted through USDA's National Veterinary Services Laboratory in Ames, Iowa, and a network of laboratories around the country.

Q. Does this new surveillance plan signify that the previous plan was not effective?

A. Absolutely not. USDA has the utmost confidence in its BSE surveillance programs. As stated earlier, USDA conducted surveillance for BSE at 47 times the international standard for low-risk countries. This augmented plan will provide further assurance to consumers and industry partners that the risk of BSE in the United States remains extremely low.

Q. Did USDA subject this surveillance plan to external review?

A. The International Review Subcommittee of the Secretary's Foreign Animal and Poultry Disease Advisory Committee and the Harvard Center for Risk Analysis reviewed our BSE surveillance plan. Each of these reviews supported the approach described in the plan.

Q. Why isn't USDA testing all cattle slaughtered in the United States?

A. We would like to stress that science simply does not support the testing of every animal, regardless of age, for BSE. First, the disease has an incubation rate of 3 to 8 years. Europe, which has a much higher prevalence of the disease, has tested more than 18 million cattle over a 2-year period and has found the disease only twice in cattle under the age of 30 months (and those two animals were 28 and 29 months old). Second, scientific experts--including those at Harvard who conducted the risk assessment for BSE--agree that, even given the find in Washington State, the disease would be

circulating at extremely low levels in the U.S. cattle population and that it is most effective to concentrate surveillance efforts on the high-risk populations. Again, we must emphasize that no matter what the prevalence of the disease in the United States, there is a series of firewalls in place that dramatically reduce any possible risk to consumers. These safeguards include the ban on all parts of animals from these high-risk populations from the food supply, along with potentially infective tissues--the so-called specified risk materials--from all cattle over 30 months of age.

Q. Where will USDA get samples for BSE surveillance testing since nonambulatory animals are banned from the human food supply?

A. USDA will continue to build on previous cooperative efforts with renderers and others to obtain samples from the targeted high-risk populations and will cover certain costs associated with collecting samples for our surveillance efforts. Through these efforts, BSE surveillance samples will be collected from any of the following locations:

a. State or federally inspected slaughter establishments
b. Custom-exempt slaughter establishments
c. Farms
d. Rendering facilities
e. Veterinary diagnostic laboratories
f. Animal feed slaughter facilities, i.e. pet food plants
g. Public health laboratories – Rabies-negative cases
h. Veterinary clinics or other sites that accredited veterinarians might utilize

The random sampling of apparently normal, adult animals will come from the 40 U.S. slaughter plants that currently handle more than 86 percent of the aged cattle processed for human consumption each year in the United States. The carcasses of these animals will be held and not allowed to enter the human food chain until negative tests results are received.

Q. Who will collect the samples?

A. Samples will be collected by authorized State or Federal animal or public health personnel, accredited veterinarians, or trained State or USDA contractors.

Q. How many laboratories will USDA contract with for testing of BSE samples?

A. USDA will use as many laboratories in its State and Federal laboratory network as needed. USDA has already made initial contacts with several labs to determine their commitment and ensure appropriate geographic distribution to meet the testing objectives from different areas of the country.

Q. Is USDA considering using private laboratories to conduct BSE surveillance tests?

A. USDA currently plans to utilize a network of State and federal veterinary diagnostic laboratories to conduct BSE surveillance tests. We believe it is important for this testing to remain in the public domain as these laboratories are an integral part of the regulatory system.

Q. Will USDA utilize BSE rapid tests?

A. USDA is working to approve rapid tests for use in the BSE surveillance program and anticipates being able to license one or more of the test kits available in the near future, with additional tests being available and subject to approval within two or three months time.

Q. Will the rapid tests be the only test used?

A. No. Any rapid test that identifies a suspect positive result will be subject to additional confirmatory testing by NVSL. USDA will continue to use the immuno-histochemistry (IHC) test, the international gold standard for BSE tests, both for some routine samples, such as those samples that are not time sensitive where the animal is being buried or incinerated, and for quality assurance testing. If a rapid test comes back with a suspect positive, then USDA will utilize the IHC or other testing methods, such as Western blot analysis, to confirm the results.

Q. Do you think you will find more cases of BSE?

A. Maybe. That is the reason for an enhanced surveillance program: to better determine the actual prevalence of BSE in the United States. The fact remains that, even if we find additional cases, the United States has an extremely effective set of firewalls in place to protect consumers--including a ban on high-risk animals from the food and feed supplies, along with a ban from the food supply of all potentially infective tissues--the so-called specified risk materials--from all cattle over 30 months of age.

The Harvard Center for Risk Analysis confirmed in two risk assessments (one originally in 2001 and a reassessment in October 2003) the importance of these firewalls and found that even if infected animals or ruminant feed material entered the U.S. animal agriculture system, the risk of it spreading extensively within the U.S. herd was low. Moreover, that any possible spread would now have been reversed by controls put in place in the late 1990's, and that eventually, the disease would be eliminated from the United States.